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PATENT COOPERATION TREATY

PCT

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

14

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
SCB/51869001		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/GB99/04311	17/12/1999	22/12/1998
International Patent Classification (IPC) or national classification and IPC C12N9/00		
Applicant JANSSEN PHARMACEUTICA N.V. et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☒ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
09/05/2000	25.07.2001
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Donath, C Telephone No. +49 89 2399 8710

Form PCT/IPEA/409 (cover sheet) (January 1994)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB99/04311

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:
Description, pages:

1-44 as originally filed

Claims, No.:

1-42 as originally filed

Drawings, sheets:

1-8 as originally filed

Sequence listing part of the description, pages:

1-4, filed with the letter of 24.02.2000

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☒ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☒ furnished subsequently to this Authority in computer readable form.
- ☒ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☒ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application.

   ☒ claims Nos. 27-29,35-40.

because:

   ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):

   ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☒ no international search report has been established for the said claims Nos. 27-29,35-40.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the standard.

   ☐ the computer readable form has not been furnished or does not comply with the standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-26,30-34,41,42
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-26,30-34,41,42
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-26,30-34,41,42
	No:	Claims	

2. Citations and explanations
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

Ad section III.:

1. Claims 27-29 and 35-37 concern a compound or agent and the use thereof in the preparation of a medicament. The compound of agent is only defined by the method which can be used in order to identify said compound or agent, respectively. Claims 38-40 concern a method comprising a compound or agent according to claims 27-29 and 35-37, or which method comprises a compound which is only defined in that it inhibits the function and/or expression of a human Akt-3 protein, and in that it binds to human Akt-3 protein, respectively. Since it is completely unclear which kind of substances will be identified by the respective methods and since in the specification no concrete examples for these kind of substances are given, the scope of said claims is totally ambiguous and undefined. Moreover, it cannot be excluded that even substances known in the art may be recognized as agents that influence or inhibit the function and/or expression of human Akt-3 protein.

   In view of the wording of the claims presently on file, which render it difficult, if not impossible, to determine the matter for which protection is sought, the present International application fails to comply with the clarity requirements of Article 6 PCT to such an extent that a meaningful search of these claims was found to be impossible.
   The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT).

Ad section V.:

1. The present international application refers to a cDNA sequence encoding human Akt-3 protein, to its amino acid sequence, and to antibodies specific for human Akt-3 protein. The cDNA, antibodies, and the human Akt-3 protein may themselves be used as medicaments, or in the preparation of medicaments for treating cancer. Furthermore, the present international application concerns methods of identifying agents which influence the activity of human Akt-3 protein.

In view of the documents cited in the international search report the subject-matter of claims 1-26,30-34,41 and 42 of the present international application has to be regarded as being new (Article 33(2) PCT).

2. The closest prior art to evaluate the inventiveness of the subject-matter of claims 1-26,30-34,41 and 42 of the present international application is document D1 (Biochemical and Biophysical Research Communications 216(2), 526-534, 1995). This document describes the molecular cloning of rat Akt-3, its nucleotide and amino acid sequence. It turned out this rat Akt-3 possesses an apparently truncated tail and thereby lacks Ser^{473}, and thus, its regulation may differ from that of Akt-1 and Akt-2, which both are expressed widely.

   In the prior art no indication has been given for a human Akt-3 protein which possesses a COOH-terminal tail that contains an amino acid residue analogous to Ser^{473}/Ser^{474} previously implicated in the activation of Akt-1/Akt-2, but absent in the rat Akt-3 protein.

   Therefore, an inventive step has to be acknowledged for claims 1-26,30-34,41 and 42 of the present international application (Article 33(3) PCT).

Ad section VIII.:

1. Claims 1,6 and 7 lack clarity due to the expressions "functional equivalent, derivative or bioprecursor thereof". These terms are not suitable to clearly define the scope of the claims, because without a precise definition of which of the possible functions of the human Akt-3 protein should be equivalent and of the properties of the derivative and the bioprecursor these expressions are absolutely vague and ambiguous.

2. Claim 5 lacks clarity due to the expressions "antisense molecule capable of ...". This term is not suitable to clearly define the scope of the claim, because without a definition of the length of said antisense fragment/molecule this expression is absolutely vague and ambiguous.

3. Claim 20 lacks clarity due to the term "antibody capable of binding to human Akt-3 protein...". Without any further technical characterization of the antibody, the antibodies already known in the art e.g. those described in document D2 (Biochemical Journal 331(1), 299-308, 1998) and any antibody known in the art which will cross react with the human Akt-3 protein is included in the scope of said claim. Moreover, an antibody being a protein has to be clearly characterized by structural and technical features.

4. Claims 17-19 lack clarity due to the term "organism". Since in the specification no specific organisms are mentioned, it should be clarified that only non-human organisms are concerned.